

*REMARKS/ARGUMENTS**Amendments*

The specification has been amended to replace each occurrence of the trademark “carbopol” with the capitalized version, “CARBOBPOL.”

The claims have been amended to recite impeding micro-vascular destruction and progression associated with burns. The claims also have been amended to more clearly and/or precisely recite the claimed method. New claims 37 and 38 have been introduced to recite methods for treating scalds and a second degree burns, respectively. New claims 39-45 have been added to recite particular ranges and amounts of ethanol. New claim 46 has been introduced to recite a temporal range for applying the composition following burn onset.

*Office Action*

The specification has been objected to on the grounds that the trademark “carbopol” is not capitalized.

Claims 19-36 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,013,545 (“Blackman et al.”) in view of U.S. Patent No. 6,656,928 (“McCadden”).

*Objection to the Specification*

As noted above, the specification has been amended to replace “carbopol” with “CARBOBPOL.” The amendment is believed to render moot the objection as to the specification. Accordingly, withdrawal of the objection is respectfully solicited.

*Obviousness Rejection*

The present invention is predicated on Applicant’s surprising and unexpected discovery that applying a composition containing 15-50 wt% ethyl alcohol and a topically acceptable polymeric carrier to a burn impedes micro-vascular destruction associated with the burn as well as burn progression. The method of the present invention effectively impedes the development of even severe burns such as, e.g., scalds and second degree burns. See, e.g., Example 1, at page 17 of the present specification, which discloses completely impeding the progress of a second degree burn, and, e.g., Example 7, at page 19 of the present

specification, which discloses impeding wound progression from a scald, using Applicant's method. The present specification provides data demonstrating that the claimed method "drastically impeded the micro-vascular destruction and progress of burn" and is even therapeutically effective when applied one hour after burn infliction. See, e.g., Example 13, from pages 22-24 of the instant specification, and Figures 2-4. No such method is taught or suggested by the cited references, individually or combined.

Blackman et al. describes applying compositions containing "from about 60 to about 90% by weight ethyl alcohol" (e.g., at col. 2, line 39) for antimicrobial applications. Blackman et al. does not disclose or suggest whatsoever impeding micro-vascular destruction or progression of burns using the compositions disclosed therein, and much less impeding micro-vascular destruction and progression of burns by applying a composition containing 15-50 wt% ethyl alcohol and a polymeric carrier as recited in the instant claims. Rather, the compositions disclosed by Blackman et al. must "contain sufficiently high concentrations of alcohol in a novel gel matrix to be bactericidal and bacteriostatic" (col. 4, lines 59-61). According to Blackman et al., "the antibacterial effectiveness of ethyl alcohol results from its denaturing of proteins" (col. 4, lines 63-65), and the disclosed compositions enhance penetration of actives "by altering the stratum corneum" (col. 5, lines 19-23).

Blackman et al. thus teaches using the disclosed compositions to alter the structure and/or function of the skin for the purpose of optimizing antimicrobial efficacy, which differs substantially from Applicant's method. One of ordinary skill in the art seeking to impede micro-vascular destruction associated with burn progression clearly would not have sought to use a method that is known to promote "denaturing of proteins" and "altering the stratum corneum" as taught by Blackman et al. Rather, one of ordinary skill in the art would have sought to avoid such effects. Blackman et al. confirms that, at the time of Applicant's invention, one of ordinary skill in the art would not have sought to use ethanol to impede micro-vascular destruction or progression of burns, and certainly would not have contemplated applying a composition containing 15-50 wt% ethyl alcohol and a polymeric carrier to impede micro-vascular destruction and progression of burns, e.g., scalds and second degree burns, as Applicant has done. Indeed, Blackman et al. confirms that Applicant's method would have been counter-intuitive in view of the art existing at the time of Applicant's invention.

The fact that Blackman et al. imposes a strict lower limit of about 60 wt% ethanol also cannot be ignored, nor can the fact that Blackman et al. explicitly distinguishes compositions containing lower ethanol concentrations. For instance, Blackman et al. states that “indeed, the concentration of alcohol in the [prior art] vehicles (30-50%) is *insufficient* to exhibit significant antimicrobial activity” (col. 1, lines 57-60, emphasis added). Blackman et al. additionally states that “the prior art does not teach topical compositions containing high concentrations of alcohol in a form which maximizes its bactericidal and antiseptic properties and enables it to act as a long term penetration enhancer for a topically active pharmaceutical agent” (col. 2, lines 10-16). Blackman et al. further states that “[t]he alcohol-containing gels of U.S. Pat. No. 4,593,048, which do not combine high alcohol concentrations with significant amounts of water, do not exhibit good bioadhesion and are not able to maintain bacteriostatic activity” (col. 5, lines 13-17).

Blackman et al. thus teaches *against* using compositions containing less than about 60 wt% ethanol. It would not therefore have been obvious to a person of ordinary skill in the art at the time of Applicant’s invention to combine the teachings McCadden so as to reduce the ethanol content required by Blackman et al., as the Office has proposed. Such a result would be contrary to the teaching of Blackman et al., and in any event would not have rendered Applicant’s invention obvious as neither Blackman et al. nor McCadden discloses or reasonably suggests impeding micro-vascular destruction and progression associated with burns, e.g., scalds or second degree burns, by applying a composition containing 15-50 wt% ethyl alcohol and a polymeric carrier as recited in the instant claims. Applicant’s method highly effectively reduces damage associated with burns, including severe burns, in a way that one of ordinary skill in the art simply would not have contemplated in view of the cited references.

Applicant understands that a judgment on obviousness may involve some level of hindsight reasoning so long as it does not rely on knowledge gleaned only from an applicant’s disclosure (M.P.E.P. § 2145(X)(4)). However, “[d]etermination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 48 USPQ2d 1321 (Fed. Cir. 1998). Simply stated, “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the

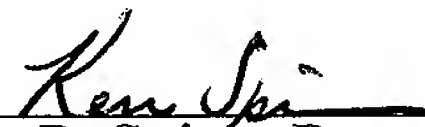
claimed invention.” *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Thus, the Office must not pick and choose from among isolated disclosures in the prior art to arrive at the claimed invention using the benefit of Applicant’s disclosure as a guide. Indeed, there is no evidence that anyone prior to Applicant’s discovery had heretofore discovered a method for impeding micro-vascular destruction and progression associated with burns by applying a composition containing 15-50 wt% ethyl alcohol and a polymeric carrier as recited in the instant claims. The cited art simply fails to disclose or suggest such a method.

Accordingly, Applicant respectfully submits that the amended claims are not obvious in view of the cited references. For at least the foregoing reasons, withdrawal of the obviousness rejection is respectfully solicited.

### *Conclusion*

Applicant respectfully submits that the present application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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